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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,504	07/25/2003	Clark C. Davis	1001.1869101	1503

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EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	PAPER NUMBER
3736	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/604,504	DAVIS ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 27-87* is/are pending in the application.

4a) Of the above claim(s) *5,9,11,12,15-17,21-24,28-52,54,56,57 and 60-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-8,10,13,14,18-20,25,27,53,55,58,59 and 76-87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 January 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Drawings

2. The drawings are objected to because Figure 4 in the drawings submitted on January 16, 2006 has not been labeled in the drawings. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-4, 6-8, 10, 14, 19, 20, 25, 27, 53, 55, 58, 59 and 76-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (6,579,246 B2) in view of Shiber (5,135,531).

Jacobsen et al disclose a coronary guidewire system and further disclose an elongate body having a proximal end, a distal end and a longitudinal axis extending at least from the proximal end to the distal end; a helical coil formed of wire (see Figures 15-17); the body comprising a tubular member (514) having a plurality of slots configured to make the tubular member (514) more flexible in bending; the first coil located at or near the distal end, the first coil substantially comprising a substantially radiopaque material (see Figures 15-17; Column 11, lines 66-67; and Column 12, lines 1-11); a core wire (501), at least part of the core wire being located inside the tubular member (514), at least a portion of the core wire (501) being located inside the first coil (see Figures 15-17); the medical device is a guidewire (see Column 2, lines 39-42); the core wire (501) being attached with a joint to the first tubular member (514) at least at the proximal end, the joint comprising a first coil circumscribing the core wire (501), the first coil being at least partially inside the first tubular member (514), and the joint comprises at least one of solder and adhesive (see Column 12, lines 9-34); the core

wire (501) being metal and the first coil is metal, the joint comprising solder attaching the first coil to the core wire (501) and adhesive attaching at least one of the first coil, the core wire and the solder to the first tubular member (514) (see Column 12, lines 9-34); the tubular member (514) comprising a plurality of slots formed in the tubular member, at least a plurality of slots being substantially perpendicular to the axis, the slots being formed in a plurality of groups, and at least a plurality of groups comprising a plurality of slots at substantially the same location along the axis (see Figure 18); the core wire (501) having a tapered portion, the joint being located at least partially within the tapered portion (see Figures 14 and 18); the core wire (501) further being attached to the first tubular member (514) at the distal end of the tubular member (514) (SEE Column 12, lines 9-34); the core wire (501) further being attached to the tubular member (514) at least one location intermediate (518) the proximal end and the distal end (see Column 12, lines 9-11); the core wire (501) comprising an abrupt change in diameter between the proximal end and the distal end (see Figure 14); radiopaque material inside the tubular member (514), at or adjacent to the distal end of the tubular member (514) (see Figure 18; Column 11, lines 66-67; and Column 12, lines 1-11); the core wire (501) being attached to the tubular member (514) at the distal tip (520) of the core wire (501); and the core wire (501) having at least one abrupt change in cross-sectional dimension, the abrupt change being at or adjacent to the joint (see Figures 14-18).

Jacobsen et al, however fail to disclose the coil being formed from a wire having a substantially non-circular cross section; and the cross section having a greater dimension in the radial direction than in the axial direction.

Shiber discloses a guided atherectomy system and further discloses the coil being formed from a wire having a substantially non-circular cross section; and the cross section having a greater dimension in the radial direction than in the axial direction. See Figure 11; and Column 6, lines 45-56.

With regards to Claims 76-87, one of ordinary skill in the art would recognize Shiber implicitly teaches a coil that is created from a trapezoidal cross-sectioned wire and when the coil is formed, the trapezoidal shape becomes a rectangular cross section. In order to obtain the rectangular cross section as taught by Shiber, the wire would have to initially be of a trapezoidal shape before being formed into the coil, because if the wire was initially of a rectangular cross section, the formed coil would be formed into a trapezoidal cross section due to the increase of material on the inside of the formed coil.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the guidewire coil of Jacobsen et al to include the use of a non-circular cross section, as per the teachings of Shiber, since it would provide another means of providing a flexible distal end for a guidewire.

5. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (6,579,246 B2) and Shiber (5,135,531) as applied to claim 7 above, and further in view of Lui (2002/0010475 A1).

Jacobsen et al and Shiber, as discussed above, disclose a guidewire means but fail to disclose the coil formed from wire having a thickness, the first coil having at least a portion of its length with a pitch of at least 1.5 times the wire thickness.

Lui discloses a means for removing an implanted lead from tissue and further disclose the coil formed from wire having a thickness, the first coil having at least a portion of its length with a pitch of at least 1.5 times the wire thickness. See Paragraph 0126.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the pitch of the coil of Jacobsen et al and Shiber to be at least 1.5 times the wire thickness, as per the teachings of Lui, since it is well known in the art to utilize certain pitches to obtain a required flexibility.

6. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (6,579,246 B2) and Shiber (5,135,531) as applied to claim 7 above, and further in view of Levine et al (2003/0009157 A1).

Jacobsen et al and Shiber, as discussed above, disclose a guidewire means, but fail to disclose the tubular member having a chamfer at the proximal end.

Levine et al disclose a flexible flow apparatus and further disclose the tubular member having a chamfer at the proximal end. See Paragraph 0153.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Jacobsen et al and Shiber to include the tube having a chamfer at the proximal end, as per the teachings of Levine et al, since it would provide a means of securing the tube to the core and coil.

7. Claim 76 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen et al (6,579,246 B2) and Shiber (5,135,531) as applied to claim 1 above, and further in view of Tsuji et al (5,181,668).

Jacobsen et al and Shiber, as discussed above, disclose a guidewire device, but fail to disclose the wire having a substantially non-circular cross section has two substantially flat opposite non-parallel sides that are out of parallel by an angle prior to forming the helical coil.

Tsuji et al disclose a guidewire device and further disclose the wire having a substantially non-circular cross section has two substantially flat opposite non-parallel sides that are out of parallel by an angle prior to forming the helical coil. See Figure 4.

It would have been obvious to one of ordinary skill in the art to utilize a wire with two substantially flat opposite non-parallel sides that are out of parallel by an angle prior to forming the coil, as taught by Tsuji et al, in place of the coil taught by Jacobsen et al and Shiber, since it would provide another means of forming a coil from a stock material.

Response to Arguments

8. Applicant's arguments with respect to claims 1-4, 6-8, 10, 13, 14, 18-20, 25-27, 53, 55, 58, 59 and 76-87 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571) 272-

4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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